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Attorneys for Plaintiffs
Warner Chilcott Laboratories Ireland Limited
Warner Chilcott Company, Inc. and
Warner Chilcott (US), LLC

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT COMPANY, INC., WARNER CHILCOTT (US), LLC and MAYNE PHARMA INTERNATIONAL PTY. LTD.,	:	Civil Action No.:
Plaintiffs,	:	
v.	:	
IMPAX LABORATORIES, INC.,	:	

MYLAN PHARMACEUTICALS INC., MYLAN INC., MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC. and URL PHARMA, INC.,	:	**COMPLAINT**
Defendants.	:	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., Warner Chilcott (US), LLC, and Mayne Pharma International Pty. Ltd. (collectively "Plaintiffs"), by their respective undersigned attorneys, bring this action against Defendants Impax Laboratories, Inc., Mylan Pharmaceuticals Inc., Mylan Inc., Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. and URL Pharma, Inc. and hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

THE PARTIES

The Warner Chilcott and Mayne Plaintiffs

2. Plaintiff Warner Chilcott Laboratories Ireland Limited ("WCLI") is a company organized and existing under the laws of the Republic of Ireland, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

3. Plaintiff Warner Chilcott Company, Inc. ("WCCI") is a company established under the laws of the Commonwealth of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

4. Plaintiff Warner Chilcott (US), LLC ("WCUS") is a limited liability company established under the laws of the state of Delaware with offices at 100 Enterprise Drive, Rockaway, NJ 07866. WCLI, WCCI, and WCUS hereinafter are referred to collectively as "Warner Chilcott".

5. Plaintiff Mayne Pharma International Pty. Ltd. ("Mayne") is a corporation organized and existing under the laws of Australia, having a principal place of business at Level 21-390 St. Kilda Road, Melbourne, Australia 3004.

6. Mayne was formerly known as F. H. Faulding & Co., Ltd.

The Impax Defendant

7. On information and belief, Defendant Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

The Mylan Defendants

8. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharma") is a corporation organized under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

9. On information and belief, Defendant Mylan Inc. is a corporation organized under the laws of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

10. On information and belief, Mylan Pharma is a wholly owned subsidiary of Mylan Inc., and the acts of Mylan Pharma complained of herein were and are aided and abetted by, and done with the cooperation, participation, and assistance of, Mylan Inc. On information and belief, Mylan Pharma and Mylan Inc. have officers or directors in common.

11. Mylan Pharma and Mylan Inc. hereinafter are referred to collectively as "Mylan."

The Mutual Defendants

12. On information and belief, Defendant Mutual Pharmaceutical Company, Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

13. On information and belief, Defendant United Research Laboratories, Inc. is a corporation organized and existing under the laws of Pennsylvania, having a principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

14. On information and belief, Defendant URL Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124. Until a name change on or about May 20, 2008, URL Pharma, Inc. was known as Pharmaceutical Holdings Corp.

15. On information and belief, Mutual Pharmaceutical Company, Inc. is a subsidiary of URL Pharma, Inc. and has common officers and directors.

16. On information and belief, United Research Laboratories, Inc. is a subsidiary of URL Pharma, Inc. and has common officers and directors.

17. Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc., URL Pharma, Inc. and Pharmaceutical Holdings Corp. are at times referred to hereinafter collectively as "Mutual".

JURISDICTION AND VENUE

18. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

19. Impax sells various products and does business throughout the United States, including in this judicial district. Impax has maintained continuous and systematic contacts in New Jersey, and has previously consented to personal jurisdiction in this district.

20. Mylan Pharma is registered to do business in the State of New Jersey. Its agent for service of process in New Jersey is Corporation Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628.

21. Mylan has submitted to jurisdiction in this judicial district in numerous patent cases in the last five years. Mylan has maintained continuous and systematic contacts in New Jersey, and sells various products and does business throughout the United States, including in this judicial district.

22. Mutual conducts business and sells various products throughout the United States, including within this judicial district.

23. On information and belief, United Research Laboratories, Inc. is registered to do business in New Jersey.

24. In a prior ANDA patent litigation, this Court ruled that it had personal jurisdiction over Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc.

25. On information and belief, Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. have previously submitted to the jurisdiction of this Court.

26. On information and belief, this Court has personal jurisdiction over Impax, Mylan and Mutual by virtue of, *inter alia*, the above-mentioned facts.

27. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF -- PATENT INFRINGEMENT

Plaintiffs' NDA and U.S. Patent No. 6,958,161

28. Mayne is the holder of New Drug Application ("NDA") No. 50-795 which relates to delayed-release tablets containing 75 mg base, 100 mg base and 150 mg base of doxycycline hyclate.

29. On or about May 6, 2005, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 50-795 for the treatment of a variety of bacterial infections as described in the product labeling. These tablets are prescribed and sold in the United States under the trademark Doryx®.

30. Mayne is the owner of United States Patent No. 6,958,161 ("the '161 Patent," copy attached as Exhibit A), entitled "Modified Release Coated Drug Preparation."

31. The '161 Patent was duly and legally issued by the United States Patent and Trademark Office on October 25, 2005. The '161 Patent claims, *inter alia*, modified release preparations of doxycycline hyclate, and is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Doryx Delayed-Release Tablets ("Doryx®").

32. The '161 Patent originally was assigned by the inventors to F. H. Faulding & Co. Limited, and subsequently assigned to Mayne.

33. Warner Chilcott has exclusive rights to market and sell product covered by the '161 Patent in the United States, including Doryx®.

Impax's Infringement And ANDA No. 90-505

34. On information and belief, Impax submitted to the FDA an Abbreviated New Drug Application ("ANDA") No. 90-505 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg ("Impax's Proposed Drug Products"), which are covered by one or more claims of the '161 Patent.

35. On information and belief, Impax submitted its ANDA No. 90-505 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Impax's Proposed Drug Products before the expiration of the '161 Patent.

36. On information and belief, Impax made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in its opinion and to the best of its knowledge, the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale, of Impax's Proposed Drug Products.

37. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Impax's Proposed Drug Products before the expiration of the '161 Patent, and Paragraph IV Certification, Impax has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Impax's Proposed Drug Products

for which Impax seeks approval in its ANDA will also infringe one or more claims of the '161 Patent.

38. Impax's Proposed Drug Products, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent. This will occur at Impax's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Impax will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

39. On information and belief, Impax did not allege in its Paragraph IV Certification that the '161 Patent is invalid under any of 35 U.S.C. § 101 *et seq*.

40. On information and belief, Impax did not allege in its Paragraph IV Certification that the '161 Patent is unenforceable.

41. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Impax's Proposed Drug Products be a date which is not earlier than the date of expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled. Furthermore, Plaintiffs are entitled to an award of damages for any commercial sale or use of Impax's Proposed Drug Products, and any act committed by Impax with respect to the subject matter claimed in the '161 Patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

42. On information and belief, Impax lacked a good faith basis for its Paragraph IV Certification when ANDA No. 90-505 was filed. Impax's ANDA and Paragraph IV Certification are a wholly unjustified infringement of the '161 Patent.

43. Impax has violated its duty of due care to avoid the known patent rights of the '161 Patent.

Mylan's Infringement And ANDA No. 90-431

44. On information and belief, Mylan submitted to the FDA ANDA No. 90-431 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Extended Release Tablets 75 mg and 100 mg ("Mylan's Proposed Drug Products"), which are covered by one or more claims of the '161 Patent.

45. On information and belief, Mylan submitted its ANDA No. 90-431 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's Proposed Drug Products before the expiration of the '161 Patent.

46. On information and belief, Mylan made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale, of Mylan's Proposed Drug Products.

47. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Mylan's Proposed Drug Products before the expiration of the '161 Patent, and Paragraph IV Certification, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's Proposed Drug Products for which Mylan seeks approval in its ANDA will also infringe one or more claims of the '161 Patent.

48. Mylan's Proposed Drug Products, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent. This will occur at Mylan's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Mylan will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

49. On information and belief, Mylan did not allege in its Paragraph IV Certification that the '161 Patent is invalid under any of 35 U.S.C. § 101 *et seq*.

50. On information and belief, Mylan did not allege in its Paragraph IV Certification that the '161 Patent is unenforceable.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mylan's Proposed Drug Products be a date which is not earlier than the date of expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled. Furthermore, Plaintiffs are entitled to an award of damages for any commercial sale or use of Mylan's Proposed Drug Products, and any act committed by Mylan with respect to the subject matter claimed in the '161 Patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

52. On information and belief, Mylan lacked a good faith basis for its Paragraph IV Certification when ANDA No. 90-431 was filed. Mylan's ANDA and Paragraph IV Certification are a wholly unjustified infringement of the '161 Patent.

53. Mylan has violated its duty of due care to avoid the known patent rights of the '161 Patent.

Mutual's Infringement And ANDA No. 91-043

54. On information and belief, Mutual Pharmaceutical Company, Inc. submitted to the FDA ANDA No. 91-043 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg ("Mutual's Proposed Drug Products"), which are covered by one or more claims of the '161 Patent.

55. On information and belief, Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc., URL Pharma, Inc. and Pharmaceutical Holdings Corp., or all or part of the foregoing, acting alone or in concert, caused, actively encouraged and/or directed Mutual Pharmaceutical Company, Inc. to file ANDA No. 91-043 with the FDA, and/or participated in the work related to the submission of ANDA No. 91-043.

56. On information and belief, Mutual submitted its ANDA No. 91-043 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Mutual's Proposed Drug Products before the expiration of the '161 Patent.

57. On information and belief, Mutual made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mutual's Proposed Drug Products.

58. By filing its ANDA under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Mutual's Proposed Drug Products before the expiration of the '161 Patent, Mutual has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for

sale, sale and/or importation of Mutual's Proposed Drug Products for which Mutual seeks approval in its ANDA will also infringe one or more claims of the '161 Patent.

59. Mutual's Proposed Drug Products, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent. This will occur at Mutual's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Mutual will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

60. On information and belief, Mutual did not allege in its Paragraph IV Certification that the '161 Patent is not infringed.

61. On information and belief, Mutual did not allege in its Paragraph IV Certification that the '161 Patent is unenforceable.

62. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mutual's Proposed Drug Products be a date which is not earlier than the date of expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled. Furthermore, Plaintiffs are entitled to an award of damages for any commercial sale or use of Mutual's Proposed Drug Products, and any act committed by Mutual with respect to the subject matter claimed in the '161 Patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

63. On information and belief, Mutual lacked a good faith basis for its Paragraph IV certification when ANDA No. 91-043 was filed. Mutual's ANDA and Paragraph IV Certification are a wholly unjustified infringement of the '161 Patent.

64. Mutual has violated its duty of due care to avoid the known patent rights of the '161 Patent.

65. This is an exceptional case and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request judgment against Impax, Mylan and Mutual as follows:

(a) Judgment that the '161 Patent remains valid and enforceable;

(b) Judgment that Impax has infringed one or more claims of the '161 Patent by filing the aforesaid ANDA and Paragraph IV Certification relating to Impax's Proposed Drug Products;

(c) Judgment that Mylan has infringed one or more claims of the '161 Patent by filing the aforesaid ANDA and Paragraph IV Certification relating to Mylan's Proposed Drug Products;

(d) Judgment that Mutual has infringed one or more claims of the '161 Patent by filing the aforesaid ANDA and Paragraph IV Certification relating to Mutual's Proposed Drug Products;

(e) An Order that the effective date of any approval of Impax's ANDA No. 90-505 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and § 505(j)(2)(A)(vii)(IV) of the Act be a date which is not earlier than the expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(f) An Order that the effective date of any approval of Mylan's ANDA No. 90-431 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and §

505(j)(2)(A)(vii)(IV) of the Act be a date which is not earlier than the expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(g) An Order that the effective date of any approval of Mutual's ANDA No. 91-043 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and § 505(j)(2)(A)(vii)(IV) of the Act be a date which is not earlier than the expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(h) A permanent injunction restraining and enjoining Impax and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Impax's Proposed Drug Products;

(i) A permanent injunction restraining and enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Mylan's Proposed Drug Products;

(j) A permanent injunction restraining and enjoining Mutual and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Mutual's Proposed Drug Products;

(k) Judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(l) To the extent that Impax has committed any acts with respect to the subject matter claimed in the '161 Patent, other than those acts expressly exempted by 35 U.S.C.

§ 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(m) To the extent that Mylan has committed any acts with respect to the subject matter claimed in the '161 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(n) To the extent that Mutual has committed any acts with respect to the subject matter claimed in the '161 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(o) Costs and expenses in this action; and

(p) Such other relief as this Court may deem proper.

Respectfully submitted,

Dated: December 23, 2008

By: /s William J. Heller

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

I hereby certify that the matter in controversy is not the subject of any other action or proceeding in any court, or of any pending arbitration or administrative proceeding.

Dated: December 23, 2008

/s William J. Heller

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